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Nos. 95-754, 95-886

IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC.,

Petitioner/Cross-Respondent,

v.

LORA LOHR AND MICHAEL LOHR,

Respondents/Cross-Petitioners.

On Writs of Certiorari to the United States Court of Appeals for the Eleventh Circuit

REPLY BRIEF FOR PETITIONER MEDTRONIC, INC.

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REPLY BRIEF FOR PETITIONER MEDTRONIC, INC.

Respondents' brief has two noteworthy features. It expends most of its energy debating an issue that has nothing to do with the language of the statute being construed: the relationship between 510(k) clearance and device safety or effectiveness. It also mischaracterizes Medtronic's position at every turn, proceeding to knock down straw men it creates without ever refuting the positions Medtronic *actually* has taken in this Court. If the Court reads the statute and Medtronic's briefs *as written*, and is not led astray by plaintiffs' diversionary tactics, it will conclude that the design defect claims in this case are preempted.

The statutory language is completely unaccommodating to plaintiffs' position. It states (21 U.S.C. 360k(a) (emphasis added)):

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, *any requirement applicable under this chapter to the device*, and
>
> (2) which *relates to* the safety or effectiveness of the device *or* to any *other* matter included in a requirement applicable to the device under this chapter.

The statute states unambiguously that the federal requirement need not relate to safety or effectiveness in order to have preemptive effect; it need only be "applicable to the device." Even the *state* requirement need not relate to safety or effectiveness; it is preempted if it relates to any other matter included in an applicable federal requirement and is different from, or in addition to, that requirement. The legislative history therefore is entirely accurate in describing Section 360k(a) as a "general prohibition on non-Federal regulation." H.R. Rep. No. 853, 94th Cong., 2d Sess. 45 (1976). Medtronic has made these

points before (see Pet. Br. 18-19, 30-31; Cross-Resp. Br. 1, 19-20, 25-27), yet plaintiffs steadfastly refuse to admit that *any* federal requirement "applicable * * * to the device" is preemptive. Instead, they debate at length whether "the 510(k) process involves a safety and effectiveness determination." Resp. Br. 29-30. But that issue is *irrelevant*; a federal requirement need only be "applicable * * * to the device" to have preemptive effect, and the 510(k) process indisputably is.[1]

In an apparent effort to persuade the Court that it matters whether the 510(k) process entails a safety and effectiveness "determination"—and that the Court should address other issues not raised by the statutory text—plaintiffs ascribe to Medtronic a host of positions that it never took.

Medtronic *never* argued that "the FDA's determination is a finding of the safety and effectiveness of the device's design." Resp. Br. 25; see also *id.* at 29-30. Such an argument would be insupportable, but it also is completely unnecessary to Medtronic's position, which is that the 510(k) process is preemptive because it imposes "requirement[s] applicable * * * to the device."[2]

Medtronic *never* attempted to show "some kind of federal *approval* for the design" of its device. Resp. Br. 24 (emphasis

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[1] Plaintiffs seriously understate the degree to which the 510(k) process and other federal requirements protect the public against unsafe or ineffective medical devices. See pp. 18-19, *infra*; Pet. Br. 5-10, 18-30. We join issue with plaintiffs on this point because the Court should not be misled (and because the Eleventh Circuit thought it important, see Pet. App. 25a-27a), but the Court need not resolve the debate; it need only conclude that the 510(k) requirements are "applicable * * * to the device" and then address the other statutory criteria, which apply to the *state* requirement. See Pet. Br. 36.

[2] The 510(k) process unquestionably *relates to* safety and effectiveness, although it need not do so in order to be preemptive. See Pet. Br. 18-30. But claiming, as Medtronic does, a relationship to safety and effectiveness is not the same as claiming that the process entails a *finding* of safety and effectiveness.

added). Medtronic showed federal *authorization* of that design, Pet. Br. 19-21, 27-28, but never claimed that the FDA would regard that authorization as an "*approval*." See *id.* at 21 n.9. And Medtronic also explained that preemption turns on applicable federal *requirements* rather than the terminology used to describe clearance for marketing. See *id.*

Medtronic *never* "claim[ed] that Congress sought to enshrine the substantial equivalence process as a permanent substitute for premarket approval for certain Class III devices." Resp. Br. 27; see also *id.* at 28. Medtronic instead explained that PMAs have not yet been required for pacemaker leads (and may never be required because they may be reclassified within the time limits Congress set in 1990 (Pet. Br. 29-30)); but none of this has anything to do with the statutory criterion, because 510(k) requirements, like PMA requirements, plainly are "applicable * * * to the device."

Medtronic *never* argued, in this Court or in the court below, that "the FDA's authority to order *labeling* changes to a marketed device would be 'different from, or in addition to' a claim regarding a device's *design*." Resp. Br. 17 (citation omitted). Neither the cited page from Medtronic's opening brief in this Court (Pet. Br. 44) nor the cited page from the opinion below (Pet. App. 28a) supports plaintiffs' assertion, and plaintiffs elsewhere recognize that Medtronic acknowledges the need for "some subject-matter congruence between the federal law that is said to preempt and the state law that is said to be preempted." Resp. Br. 21-22. Showing such a relationship is the whole point of the lengthy portions of Medtronic's prior briefs describing federal requirements applicable specifically to design, labeling, and manufacturing—the three subjects of plaintiffs' claims. See Pet. Br. 18-30; Cross-Resp. Br. 21-24, 31-34.

Medtronic *never* argued that "*all* state laws regarding medical devices" are preempted. Resp. Br. 19; see also *id.* at 16. States may retain considerable freedom, for example, to regulate medical device pricing or to apply certain aspects of state

contract law to medical devices. See Cross-Resp. Br. 18 n.18. The preemption of state tort law surely *is* broad, but that is the inevitable consequence of coupling a "general prohibition on non-Federal regulation" (H.R. Rep. No. 853, at 45) with this Court's longstanding recognition that "regulation can be as effectively exerted through an award of damages as through some form of preventive relief" (*San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 247 (1959)).

Medtronic *never* argued that "Congress' purpose" in the MDA was "simply to encourage the marketing of medical devices." Resp. Br. 38. Instead, as plaintiffs elsewhere concede (see *id.* at 37), Medtronic consistently has said that the MDA created a *balanced* regulatory scheme that *both* encourages device innovation and availability *and* protects consumers from unsafe and ineffective devices. It is plaintiffs, not Medtronic, who only discuss one statutory purpose. See Cross-Pet. Br. 3, 28-29; Resp. Br. 38-39. Plaintiffs simply are wrong, not only because the legislative history recognizes other purposes, but also because there would be no rationale whatever for the enactment of the preemption clause *itself* if plaintiffs' view of the statute were correct.

Finally, Medtronic *never* made the free-standing policy arguments that plaintiffs attack at pages 12-15 of their second brief, and certainly never argued that "whenever Congress sought to regulate a particular product and preempt state positive law, all common-law actions that provided a remedy for injuries caused by that product would be swept away." Resp. Br. 14. Medtronic argues that plaintiffs' common law claims are preempted because *Congress said so* in an express preemption clause, not because common law claims are preempted whenever Congress regulates a product.

One other pervasive misimpression created by plaintiffs deserves comment before we address each statutory criterion in turn. Plaintiffs depict an imaginary world in which there are "devices wholly unregulated by federal law" (Resp. Br. 37 n.11,

24) and devices for which "federal regulation is only a remote possibility, not a reality" (*id.* at 36). Those flights of rhetoric have no basis in fact. *Every* medical device, including devices introduced before 1976, is regulated under the MDA. See App., *infra*, 1a. The *degree* of regulation may vary depending upon the classification and intended use of the device, with PMA-approved devices more heavily regulated than 510(k) devices, Class III prescription devices such as the Model 4011 more heavily regulated than other 510(k) devices (see HIMA Br. 18-19), and 510(k) devices in turn more heavily regulated than pre-MDA devices (see App. 1a). But completely unregulated devices are as fictional as unicorns. Furthermore, if unregulated medical devices *did* exist, there would be no preemption of state law, because there would be no federal requirement "applicable to the device"; Medtronic never has contended otherwise. In any event, the device in the case before the Court is the Medtronic Model 4011 pacemaker lead, which is heavily regulated, as Medtronic demonstrated in its first two briefs. As we again show, plaintiffs' claims that the lead was defectively designed satisfy every statutory criterion for preemption.

I. THE REQUIREMENTS OF THE 510(K) PROCESS HAVE PREEMPTIVE EFFECT

Although they argue at length that the 510(k) requirements are not preemptive, plaintiffs largely ignore the statutory language stating that *any* FDCA requirement "applicable to the device" may preempt state law. Plaintiffs refuse to discuss two sections of the FDCA cited in Medtronic's opening brief, which characterize Section 510 as imposing "requirements" that are "appl[icable] to the device" and thereby confirm that the 510(k) requirements are preemptive. See Pet. Br. 31-32; 21 U.S.C. 360c(d)(2)(A), 360j(a); cf. U.S. Br. 24 n.19 (conceding that the GMP regulations are preemptive precisely because other sections of the FDCA describe them as "requirements"). Instead, plaintiffs merely reiterate their assertion that federal requirements are not preemptive unless they are device-specific, because the statute refers to requirements "applicable to *the*

device." Although Medtronic will not repeat its previous responses to plaintiffs' strained construction (see Pet. Br. 33-36; Cross-Resp. Br. 25-27), three additional points are worth noting.

First, plaintiffs misread the preemption provision by construing a reference to "*the* device" as a statement that only device-specific federal requirements are preemptive. The preemption provision prohibits defined state requirements "with respect to *a* device" if there is a federal requirement "applicable * * * to *the* device." 21 U.S.C. 360k(a) (emphasis added). This use of the definite article does nothing more than clarify, sensibly, that a federal requirement must apply to the *same* device as a state requirement it preempts.

Second, plaintiffs rely for their interpretation on an agency regulation (21 C.F.R. 808.1(d)) and, incredibly, argue that this Court should accord it "substantial deference" (Resp. Br. 19) even though the FDA, through the Solicitor General, has abandoned the regulation and agreed with Medtronic that the statute does not restrict preemptive federal requirements to those that are device-specific. Cross-Resp. Br. 26-27; U.S. Br. 24 n.19, 25 n.20. Because even the FDA agrees that the statute is inconsistent with plaintiffs' construction of the regulation, there is no basis for deference. Cf. *Public Employees Retirement Sys. of Ohio* v. *Betts*, 492 U.S. 158, 171 (1989).[3]

Third, plaintiffs briefly refer to the Solicitor General's argument that the design *specifications* for the Model 4011 are not requirements applicable to the device "under *th[e Act]*," because they originated in voluntary decisions of the

[3] Plaintiffs are incorrect even in their interpretation of the regulation. As the Eleventh Circuit correctly concluded (in line with the explicit or implicit rulings of eight other courts of appeals), the language of the FDA's regulation "does not suggest that the requirements themselves must mention the particular device in question" to be preemptive. Pet. App. 19a. This construction is consistent with another section of the same regulation stating that the GMP regulations (which apply to thousands of devices) may preempt state law. See 21 C.F.R. 808.1(d)(6)(i).

manufacturer. Resp. Br. 23; U.S. Br. 20. As Medtronic explained in its first brief, however, once a device's design is submitted to and authorized by the FDA, federal regulations prohibit *changes* that could significantly affect safety or effectiveness without agency clearance; what *starts out* as a voluntary decision thus becomes a binding and limiting federal requirement.[4] The 510(k) requirements that regulate device design unquestionably are "applicable under [the FDCA] to the device," and they therefore are preemptive.

II. PLAINTIFFS' CLAIMS WOULD ESTABLISH STATE REQUIREMENTS WITHIN THE MEANING OF THE PREEMPTION PROVISION

A. Plaintiffs' Claims Would Establish "Requirements"

Medtronic explained in its first two briefs why the language of the statute, informed by this Court's decision in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992), shows that plaintiffs' claims would establish "requirements" subject to preemption. Pet. Br. 36-39; Cross-Resp. Br. 9-12; see also U.S. Br. 15-19 (common law duties are state "requirements" under Section 360k(a)). One new point raised by plaintiffs deserves a short response. According to plaintiffs, the holding in *Cipollone* depends fundamentally upon differences in language between the Public Health Cigarette Smoking Act of 1969 and a predecessor statute with a preemption provision limited to positive law. Resp. Br. 7-9. This argument is absurd, because it

[4] The government also mischaracterizes the Model 4011's design specifications by implying that there are no federal requirements affecting those specifications and comparing them to the voluntary contract terms at issue in *American Airlines, Inc.* v. *Wolens*, 115 S. Ct. 817 (1995). U.S. Br. 20-21. Although the Model 4011's specifications did not originate from the FDA, they are not "privately ordered obligations" analogous to the terms of a contract. Cf. *id.* at 824. In order to pursue marketing under the 510(k) process, Medtronic had to design the Model 4011 in accordance with the statutory requirement that it must be substantially equivalent to a preamendment device. See Pet. Br. 19-27.

suggests that a statute with the same language as the 1969 Act (such as the FDCA) would not preempt common law claims in the *absence* of a predecessor statute. There is no justification for demanding a prior enactment as a prerequisite for interpreting the plain language of the statute as extending to common law claims.[5]

B. Plaintiffs' Claims Would Impose Requirements Established by a "State or Political Subdivision"

As is typical throughout their brief, plaintiffs discuss the wrong issue when they assert that "Medtronic must demonstrate that *a jury award* in a medical device case is issued by a 'State or political subdivision of a State.'" Resp. Br. 10 (emphasis added). The question is not whether a *jury award* establishes or continues in effect state requirements, but whether *state common law* establishes or continues in effect requirements that a judge or jury enforces by awarding relief in a tort action involving a medical device. And that is not a difficult question; this Court answered it definitively nearly sixty years ago.

"At least since *Erie R. Co.* v. *Tompkins*, 304 U.S. 64 (1938), [the Court has] recognized the phrase 'state law' to include common law as well as statutes and regulations." *Cipollone*, 505 U.S. at 522. Thus, in *Cipollone* and again in *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658 (1993), the Court rejected plaintiffs' assertion that the State has not acted when judges and juries resolve common law claims. In *Easterwood*, the Court affirmed preemption of common law claims under a Federal Railroad Safety Act provision that bars "[a] State" from "adopt[ing] or

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[5] Plaintiffs also ignore the legislative history of the FDCA preemption provision, which involved changes in statutory language directly analogous to the changes between the two statutes at issue in *Cipollone*. The Senate bill that preceded the MDA limited preemption to positive state law, prohibiting "any provision of a standard or regulation which prescribes any requirements" regarding certain enumerated subjects. 121 Cong. Rec. S 6161- S 6162 (daily ed. Apr. 17, 1975). The final bill drafted by the Conference Committee, of course, broadened the language and used the term "requirement."

continu[ing] in force" certain railroad safety standards. 507 U.S. at 662 n.2, 673-76. This language is in relevant respects indistinguishable from the FDCA.

Furthermore, plaintiffs' argument that there can be no preemption in federal diversity cases does not withstand scrutiny. See Resp. Br. 10-11. That argument is flatly foreclosed by *Easterwood*, in which this Court affirmed preemption under the statutory language quoted above in a federal diversity suit. See 507 U.S. at 661. Federal judges and juries sitting in diversity, no less than state judges and juries, apply "requirement[s]" "establish[ed] or continue[d] in effect" *by the State*. See *Guaranty Trust Co. of New York* v. *York*, 326 U.S. 99, 108-09 (1945) (federal court sitting in diversity is, "in effect, only another court of the State"). Plaintiffs' argument would lead to the absurd conclusion that federal courts may apply otherwise-preempted state common law but state courts may not. That reading of the preemption provision is neither sensible nor consistent with its language.

III. PLAINTIFFS' CLAIMS ARE PREEMPTED BECAUSE THEY WOULD ESTABLISH STATE REQUIREMENTS "DIFFERENT FROM, OR IN ADDITION TO," THE 510(K) REQUIREMENTS

A. The 510(k) Requirements Regulate Device Design

Plaintiffs' argument hinges on the assertion that the 510(k) process "does not impose requirements that relate in any way to device design." Resp. Br. 6; see also *id.* at 15-24. They further argue that, if there is no federal requirement relating to device design, any state requirement established through their design claims could not properly be characterized as "different from, or in addition to," a federal requirement. *Id.* at 24. But plaintiffs *completely ignore* the sections of Medtronic's opening brief explaining that a design is marketable under the 510(k) process only if it is substantially equivalent to a preamendment device and that manufacturers must submit design information for FDA review (Pet. Br. 22-23); plaintiffs also refuse to acknowledge

that 510(k) premarket clearance depends fundamentally upon the FDA's comparison of the designs of the device under review and the predicate device (*id.* at 23-25).

What plaintiffs are really arguing is that there can be no federal requirements relating to device design unless those requirements *specify* the design. See Resp. Br. 22. As Medtronic explained in its opening brief, however, there is no basis in the statutory language for limiting preemption to circumstances in which there are particular federal design specifications. Pet. Br. 32-36. And, because the 510(k) requirements plainly regulate device design, there is more than adequate basis for determining that plaintiffs' design claims would establish state requirements that are "different" or "addition[al]."

B. Plaintiffs' Claims Are Preempted Because They Would Expose Medtronic to Liability for Marketing a Federally Authorized Design

Medtronic's opening brief explained that plaintiffs' claims would establish state requirements that are *by definition* "different from, or in addition to," federal requirements, because their premise is that the design authorized under the 510(k) requirements violates common law duties. Pet. Br. 44-46. Implicitly recognizing that state requirements *are* preempted if they challenge a federally authorized design, plaintiffs strain to assemble an argument from law review commentaries that 510(k) clearance is not an authorization to market at all. See Resp. Br. 24-25 & n.8. This argument completely mischaracterizes the 510(k) process.

Although plaintiffs note correctly that one purpose of the 510(k) process is to notify the FDA that a company wishes to market a device, they incorrectly assert that the FDA does not need to determine substantial equivalence before marketing may proceed. Resp. Br. 24. From the time the 510(k) process was established, the Agency has made clear that "[t]he requirements of section 510(k) of the act are intended not only to notify FDA that a device is about to be marketed but *primarily* to enable

FDA to determine whether the device is substantially equivalent to one already in commercial distribution." 42 Fed. Reg. 42,520, 42,523 (Aug. 23, 1977) (preamble to 510(k) regulation) (emphasis added); see also *id.* at 42,524 ("[S]ection 510(k) of the act is more than a notification provision."). In addition, since before the 1990 Amendments, the FDA has acted to bar marketing by *rescinding* 510(k) clearance (Pet. Br. 21), yet plaintiffs do not (and cannot) explain how this control over market access could derive from a simple "notification."

As Medtronic explained in its opening brief, the statute bars marketing if the manufacturer has not filed a 510(k) submission, or if a submission is filed but the FDA determines that the device is not substantially equivalent to a preamendment device. See Pet. Br. 19-20. The statute also explicitly bars marketing for ninety days after filing of the 510(k) submission unless the FDA grants clearance sooner. *Id.* at 20. And the FDA *did* grant clearance for the Model 4011 before this ninety-day period ended, authorizing immediate marketing in a letter that stated "[y]ou *may*, therefore, market your device" and conditioning the clearance upon compliance with "the general controls provisions of the Federal Food, Drug, and Cosmetic Act." R1-37-Exh. A to Exh. 1 (emphasis added), *quoted in* Pet. Br. 20.

Although the FDA *did* determine substantial equivalence for the Model 4011, and *did* authorize marketing, plaintiffs (citing law review articles) assert that these FDA actions were not *required* before marketing could proceed. Resp. Br. 24 & n.8. Although they acknowledge that the submission must "explain[] the basis for [the manufacturer's] claim of substantial equivalence" (Cross-Pet. Br. 35), and debate at length the details of the standards the Agency applies to determine substantial equivalence (*id.* 34-35; Resp. Br. 29-35), plaintiffs assert that Congress established a system in which agency review of the submission is only voluntary.

Plaintiffs' argument is nothing more than an unwarranted and insupportable attack on the FDA's administration of the

statute. In fact, the Agency consistently has interpreted the statute to require it to act on every 510(k) submission. See, e.g., 41 Fed. Reg. 37,458, 37,461 (Sept. 3, 1976); see also 42 Fed. Reg. at 42,524 ("[t]he Commissioner *must* determine" substantial equivalence) (emphasis added). And until the FDA *does* find that a device is substantially equivalent to a preamendment device, marketing is barred without an approved PMA.[6] As a result, even if the FDA had failed to act on a 510(k) submission at the time of the Model 4011's clearance, the statute would *not* have allowed marketing; a manufacturer that marketed under those circumstances would have violated the statutory provisions barring marketing in the absence of a required PMA. See 21 U.S.C. 351(f)(1)(B) (1982).

Finally, plaintiffs' characterization of the 510(k) process leads them to an absurd result. Plaintiffs conclude that the FDCA preserves state law requirements, even if they would "remove[] the Model 4011 from the market entirely," Resp. Br. 28, even though the FDA has authorized marketing of the device's design under federal law.[7] Plaintiffs' rationale is fundamentally inconsistent with a long line of cases (including *Fidelity Fed. Savings & Loan Ass'n* v. *De la Cuesta*, 458 U.S. 141, 155-56 (1982), and the Court's most recent preemption decision, *Barnett Bank* v. *Nelson*, No. 94-1837 (Mar. 26, 1996)) holding

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[6] See, e.g., *United States* v. *An Article of Device*, 607 F. Supp. 990, 998 (W.D. Mich. 1985). In the 1990 Amendments, Congress confirmed that manufacturers always have been required to obtain a finding of substantial equivalence before marketing is legal without an approved PMA. S. Rep. No. 513, 101st Cong., 2d Sess. 19 (1990) (1990 amendments confirm that under the original statute, a device "automatically" requires PMA approval "unless the Secretary finds that it is substantially equivalent to a device which is not subject to a premarket approval requirement").

[7] As Medtronic has explained previously, the 510(k) clearance is an authorization to market the proposed *design* as well as the device itself, because the FDA has reviewed and cleared a particular design, which may not be changed, without further agency clearance, in a manner that could significantly affect safety or effectiveness. Pet. Br. 27-28.

that if federal law authorizes particular conduct, state law barring the same conduct is impliedly preempted because it frustrates the congressional purpose. The FDCA express preemption provision mandates even *broader* preemption than does the implied preemption doctrine by invalidating state law if it is "different from, or in addition to," federal requirements, regardless of whether the differences or additions are significant enough to frustrate the congressional purpose. Because plaintiffs' claims, if successful, would require Medtronic to pay damages under state law for marketing a device design authorized by federal law, they are preempted.

C. Plaintiffs' Claims Are Preempted Because They Would Require Medtronic to Change the Design of the Model 4011

The statutory phrase "different from, or in addition to," does not demand a direct conflict between federal and state law as a prerequisite for preemption, yet there is a direct conflict in this case. Although plaintiffs again re-argue points resolved against them in *Cipollone* (Cross-Resp. Br. 9-12) and assert that the requirement to pay damages has no regulatory effect (Resp. Br. 12-14, 36), their claims, if successful, would require Medtronic to redesign its device to avoid future liability, Pet. Br. 44-46. And the requirements of the 510(k) process would bar those changes without further FDA clearance, which might not be obtained. *Id.* at 45 & n.21. The feebleness of plaintiffs' response to this point is quite telling.

First, plaintiffs make the specious argument that the changes demanded by state law could be too insignificant to require FDA clearance. Resp. Br. 35-36. The applicable federal regulation requires 510(k) clearance for *any* change "that could significantly affect * * * safety or effectiveness." 21 C.F.R. 807.81(a)(3)(i). Surely plaintiffs do not mean to suggest that state law would support an award of damages to Mrs. Lohr for a design "defect" with *no* significant effect on safety and effectiveness, yet that is the logic of their position. If plaintiffs'

claims were successful, to avoid future liability for negligence, Medtronic would need to change its design to make it reasonably safe for use in a foreseeable manner; to avoid future strict liability, Medtronic would need to change the design so that it was not unreasonably dangerous to foreseeable users. See Pet. Br. 42. It is absurd to argue that these changes, which focus on the essential safety of the device, "could not" significantly affect safety or effectiveness.

Second, the Court should reject plaintiffs' assertion that preemption could not be determined until the FDA denied clearance for the design changes required by state law. Resp. Br. 36. The 510(k) requirements bar relevant changes *unless and until* the FDA authorizes them. Thus, from the moment Medtronic obtained initial marketing clearance for the Model 4011, the changes plaintiffs' claims demand were prohibited. And although a subsequent FDA clearance for the change theoretically could resolve the conflict, it would be nonsensical to suggest that Congress intended such clearance to "undo" preemption; under these circumstances, the state requirements would still be preempted, because they would be "in addition to" the federal requirement. See Cross-Resp. Br. 38-50. The mechanism Congress placed in the statute to "undo" preemption is the *prospective* exemption provision of Section 360k(b) (allowing the FDA to preserve otherwise-preempted state requirements), not the intricate backward-looking procedure plaintiffs suggest.

Third, plaintiffs assert that their claims are not preempted because Medtronic could cease marketing the Model 4011, thereby avoiding imposition of different or additional state requirements. Resp. Br. 36. In *Cipollone*, *Easterwood*, and numerous other preemption cases, the defendant also could have avoided imposition of inconsistent state and federal requirements by discontinuing activity that the federal law allows, yet the Court nonetheless affirmed preemption. Furthermore, the resolution that plaintiffs suggest is particularly untenable under the FDCA preemption provision, because its entire purpose is to

prevent state law from driving valuable devices such as the Model 4011 off the market or discouraging their innovation. It is ridiculous to suggest that a provision enacted for this purpose would deny preemption by inducing manufacturers to stop marketing potentially life-saving devices.[8]

IV. PREEMPTION IS CONSISTENT WITH THE STATUTORY SCHEME

Plaintiffs' view of the statute presents a fundamental contradiction. On the one hand, plaintiffs identify a single purpose for the MDA—protection of consumers in light of public health tragedies associated with the Dalkon Shield "IUD." Cross-Pet. Br. 3. On the other hand, they argue that the 510(k) process (which applies to 98 percent of the new devices entering the market each year, see Cross-Pet. Br. 44) does not regulate safety and effectiveness at all and leaves the public completely at risk. Plaintiffs' view of the MDA renders the statutory scheme irrational, because it mandated that the majority of new devices (i.e., those in Class I and II) *must* enter the market through the 510(k) process. Plaintiffs also cannot explain why, if the statute is focused exclusively on enhancing safety and effectiveness, the preemption provision's text prohibits state requirements that "relate[] to * * * safety or effectiveness" (21 U.S.C. 360k(a)) even if they are "more stringent than a requirement under [the FDCA]" (*id.* § 360k(b)). Indeed, under plaintiffs' reading of the statute, the preemption provision has no ascertainable purpose at all.

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[8] The Court also should reject plaintiffs' suggestion that manufacturers might simply endure tort judgments *without* taking a device off the market, because "it is often beneficial to society as a whole both to keep the product on the market *and* to compensate injured parties through the tort system." Resp. Br. 13. In the real world, tort suits have created a powerful incentive to discontinue marketing of valuable medical devices, as the amicus brief of the Health Industry Manufacturers Association explains. HIMA Br. 25-28. Moreover, the decision to continue marketing a device found to be defective might subject a manufacturer to crippling punitive damages awards.

Plaintiffs' construction also deems the FDA's administration of the statute irrational, because the Agency has chosen to regulate some Class III devices, such as pacemaker leads, through the 510(k) process for the time being rather than requiring PMAs. Moreover, given their characterization of the 510(k) process, plaintiffs can offer no rational explanation why the FDA, following the Dalkon Shield tragedy, continued to regulate IUDs through the 510(k) process for a decade after Congress enacted the MDA, although the Agency could have required PMAs years earlier. See 21 C.F.R. 884.5360(d) (imposing PMA requirements for IUDs on August 4, 1986).

In fact, the statute establishes a very rational plan, and the preemption provision has an overwhelmingly important purpose. The statute promotes the health of the society as a *whole* by substituting a protective federal scheme (which promotes device innovation and availability) for the right of *individuals*—such as Mrs. Lohr—to seek relief under state law for injuries from medical devices. Congress understood that excessive state regulation (whether through common law claims or positive law) would threaten the greater good by inhibiting new technological advances and driving existing beneficial technologies off the market. Under the statute, the interests of the *few* in obtaining tort compensation give way to the interests of the *many* who benefit from life-enhancing technologies made more available by a broad "prohibition on non-Federal regulation." H.R. Rep. No. 853, at 45. The preemption of common law claims therefore is not an inadvertent by-product of the statute, but instead the result of a well-reasoned structure that fosters providing the society at large with the most advanced technology to enhance public health.[9]

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[9] The present case is easily distinguishable from *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984), in which the Court construed a statute that strikes a different balance between state and federal law than does the FDCA. Although acknowledging a "tension" between state damages actions and exclusive federal regulatory authority (464 U.S. at 256), the Court in *Silkwood*

(Footnote cont'd on next page)

In reaching this decision, Congress tailored the preemption provision to the particular characteristics of the relatively young medical device industry, which was then, as it is now, comprised largely of small, innovative companies. See, e.g., MDMA Brief 6. These small companies, most burdened by excessive regulation, historically have been the major source of innovation in the industry. See H.R. Rep. No. 853, at 12, 33 (recognizing contribution of small manufacturers to important innovations). Although plaintiffs may speculate about why Congress did not also enact an express preemption provision applicable to the products of other FDA-regulated industries, see Resp. Br. 2-3, it is clear that the device industry's vulnerability to over-regulation (and the resulting adverse consequences for public health) motivated the enactment of Section 360k.[10] In any event, it is clear that Congress *did* enact a preemption provision for medical devices, but not for various other FDA-regulated products, and this is not the proper forum to debate Congress's wisdom in making these legislative choices.

(Footnote cont'd from previous page.)

held that there was no preemption because it found that "Congress intended * * * to tolerate [such] tension" (*ibid.*) under the Atomic Energy Act of 1954. In particular, the Court read the Price-Anderson Act—which establishes an indemnification scheme for nuclear operators held liable under state tort law—to constitute affirmative evidence of Congress's acceptance of state tort actions (*id.* at 251-256). Furthermore, the Atomic Energy Act contains no preemption provision and in fact explicitly preserves significant authority for the states (e.g., 42 U.S.C. 2018, 2021(b), 2021(k)).

In addition, the sole question in *Silkwood* was whether federal law preempted state *punitive* damages awards. It was common ground among the Justices that Congress intended to permit state tort claims for *compensatory* damages. Thus, *Silkwood* involved the availability of a particular remedy, not the question whether a state tort action was foreclosed by federal law.

[10] The same concern led Congress to include a provision in the MDA establishing a specific FDA office to assist small manufacturers. See Pub. L. No. 94-295, sec. 10, 90 Stat. 539, 583 (1976).

Furthermore, to ensure prompt protection from over-regulation, Congress made the preemption clause effective immediately upon enactment of the MDA, without waiting for the FDA to promulgate regulations. See, e.g., H.R. Rep. No. 853, at 45-46 (California PMA statute preempted). But see Resp. Br. 27-28 (asserting that, until federal PMAs are in place, states may require PMAs for some devices). To be sure, Medtronic agrees with plaintiffs that a federal requirement must exist for the preemption clause to apply. But the statute itself imposed numerous requirements at the time of enactment, and the number of requirements has grown subsequently as the Agency has promulgated new regulations. In any event, extensive federal requirements certainly were in place regulating the design of the Model 4011 by the time the FDA authorized its marketing.

Finally, just as it prohibited *state* requirements through the preemption provision, Congress substantially augmented the *federal* regulatory structure to meet its goal of protecting the public from unsafe and ineffective devices. Substantive requirements such as the GMP and labeling regulations are integral to Congress's plan. The 510(k) process also is fundamental to this structure. For devices such as the Model 4011, the 510(k) process assures that safety and effectiveness is comparable to that of a preamendment device. Pet. Br. 23-27.

In order to make certain that this comparative level of safety and effectiveness is meaningful, Congress and the FDA have established a panoply of federal requirements governing the safety and effectiveness of preamendment devices. Through these requirements, some of which are described in Medtronic's opening brief and the attached appendix, the FDA has broad authority to take unsafe and ineffective preamendment devices off the market. Pet. Br. 5-10; App. 1a. By assuring safety and effectiveness comparable to a preamendment device, the 510(k) process bars marketing of devices less safe or effective than those that have stood the test of time in a heavily regulated marketplace. Plaintiffs' pretense that these substantial requirements governing preamendment devices do not exist (see

Resp. Br. 24, 37 n.11) and disingenuous suggestion that premarket clearance provisions are the *only* means of protecting the public from risky devices, simply ignore significant requirements that (in conjunction with the 510(k) process) are designed to promote the safety and effectiveness of 510(k) devices.[11]

The statute's language, structure and legislative history demonstrate that Congress struck a delicate balance between the need for enhanced federal requirements and the need to prohibit state requirements. Although reasonable people may disagree whether the 510(k) process and the allied protective requirements are the ideal system for regulating device safety and effectiveness, that issue is not before the Court. As long as those requirements are applicable to the Model 4011, they are preemptive. This Court should follow the mandate of the statutory language and conclude that plaintiffs' design claims are preempted, because they would impose state requirements relating to device design that are different from, or in addition to, those federal requirements.

CONCLUSION

The Court should reverse in part the judgment of the Eleventh Circuit and hold that the FDCA preempts plaintiffs' design defect claims.

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[11] Indeed, plaintiffs' selective presentation of the federal requirements leads to the absurd conclusion that the FDA would be powerless to prevent the marketing of a 510(k) device if it is substantially equivalent to an *unsafe* preamendment device. Resp. Br. 34-35. Under these circumstances, the FDA merely would inform the applicant that, although the device under review is substantially equivalent, it would violate other FDCA provisions to market the device. See, e.g., HIMA Br. App. B; cf. 21 U.S.C. 360c(i)(2) ("A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.").

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APPENDIX

APPENDIX: SELECTED DEVICE REQUIREMENTS

REQUIREMENT	PRE[a]	510(k)	PMA
Adulteration[1]	X	X	X
Misbranding[2]	X	X	X
Labeling (general)[3]	X	X	X
Labeling (prescription)[4]	X	X	X
Good Manufacturing Pract.[5]	X[b]	X[b]	X
Notification of Hazard[6]	X	X	X
Repair, Replace, Refund[7]	X	X	X
510(k) Clearance[8]		X	
Medical Device Reporting[9]	X[c]	X[c]	X
Device Listing[10]	X[c]	X[c]	X
Seizure, Injunction[11]	X	X	X
Factory Inspection[12]	X	X	X

Note: X denotes that requirement applies to device type.

[a] Preamendment device.

[b] FDA has statutory authority to exempt Class I devices from this requirement and has exercised that authority by regulation for numerous device types.

[c] FDA has statutory authority to exempt Class I devices from this requirement but has not yet granted any exemptions by device type.

[1] 21 U.S.C. 351 (7 separate requirements).

[2] 21 U.S.C. 352 (10 separate requirements).

[3] 21 U.S.C. 321(n), 352, 360f(a)(2); 21 C.F.R. Pts. 1, 801.

[4] 21 U.S.C. 321(n), 352, 360f(a)(2); 21 C.F.R. Pts. 1, 801.

[5] 21 U.S.C. 351(h), 360j(f); 21 C.F.R. Pt. 820.

[6] 21 U.S.C. 352(t), 360h(a).

[7] 21 U.S.C. 352(t), 360h(b).

[8] 21 U.S.C. 352(o), 360(k), 360c(f)(1), 360c(i); 21 C.F.R. Pt. 807.

[9] 21 U.S.C. 352(t), 360i; 21 C.F.R. Pt. 803.

[10] 21 U.S.C. 352(o), 360(j); 21 C.F.R. Pt. 807.

[11] 21 U.S.C. 331, 332, 334.

[12] 21 U.S.C. 374.